

Applicant : Vincent P. Stanton, Jr.  
Serial No. : 09/658,659  
Filed : September 8, 2000  
Page : 28

Attorney's Docket No.: 11926-015001

### REMARKS

#### Objection to the Specification

The Examiner objected to the specification for allegedly attempting to incorporate essential subject matter by reference. The Examiner stated that in order to conduct a proper search, the wild-type sequence of the various genes must be included in the application.

Table 10 of the specification provides the GenBank Accession Number for each of the 16 wild-type genes. Table 10 also provides the location and identity of each sequence variance referred to in the pending claims. Thus, Applicant believes that the specification includes all of the information required to conduct a thorough prior art search. However, to facilitate rapid examination of the pending claims, Applicant will submit an amendment to the specification providing a Sequence Listing under 37 C.F.R. §1.821, along with a request to incorporate the sequence listing into the application.

#### Rejections Under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 1-16 as allegedly failing to meet the written description requirement of 35 U.S.C. §112, first paragraph. The Examiner stated that

[A]ssuming *arguendo*, that the wild-type sequences identified via a GenBank repository number, were all from a human, or constitute a consensus sequence derived from a number of humans, the specification has not been found to provide an adequate written description of other wild-type versions of the coding sequence as found in other life forms, much less identify regions of variance therein and lesser still the probes encompassed by the claims of the subject application. For the above reasons, and in the absence of evidence to the contrary, the subject application has not been found to reasonable suggest that applicant was in possession of all the probes claimed.

The presently pending claims are drawn to probes comprising at least 15 contiguous nucleotides of one or another of the 16 disclosed human genes referred to in Table 10. Each probe includes one or more of the sequence variances in these 16 genes disclosed in Table 10. Thus, the specification provides an adequate written description of the claimed probes and methods.

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Page : 29

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Rejections Under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 1-4, 7, 10, 11 and 14-16 as indefinite. Claims 1-16 have been cancelled. The newly added claims are believed to be definite. These new claims avoid the phrasing objected to by the Examiner in the previously pending claims.

Rejections Under 35 U.S.C. §102(e)

The Examiner rejected claims 1-5, 8, 11-13 and 15 under 35 U.S.C. §102(e) as allegedly anticipated by Gonzalez et al. (U.S. Patent 6,015,673).

Claims 1-5, 8, 11-13, and 15 have been cancelled. The newly added claims are drawn to probes which include at least 15 contiguous nucleotides of human dihydropyrimidine dehydrogenase (SEQ ID NO:3) and include at least one specific variance listed in Table 10. It is not believed that any of the variances in Table 10 are disclosed by Gonzalez et al. Accordingly, Gonzalez et al. cannot anticipate any of the presently pending claims.

In view of the forgoing, Applicant respectfully requests that the rejections under 35 U.S.C. § 102(e) be withdrawn.

Rejections Under 35 U.S.C. §103

The Examiner rejected claims 1-9, 11-13 and 15 as allegedly obvious in view of Gonzalez et al. (U.S. Patent 6,015,673) taken with Billing-Medel et al. (U.S. Patent No. 6,130,043). The Examiner stated that it would have been obvious to use the PNA analogs and fluorescent labels of Billing-Medel et al. in the methods of Gonzalez et al.

Gonzalez et al. was discussed above. Billing-Medel et al. adds nothing of significance to Gonzalez et al. with respect to the presently claimed invention. Billing-Medel et al. does not disclose any of the variances specified in the present claims. Thus, Gonzalez et al. and Billing-Medel et al., no matter how combined, cannot render any of the present claims obvious.

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Serial No. : 09/658,659  
Filed : September 8, 2000  
Page : 30



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APR 16 2001

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The Examiner rejected claims 1-5, 8 and 10-16 as allegedly obvious in view of Gonzlez et al. (U.S. Patent 6,015,673) taken with Kaneda et al. (*J. Biol. Chem.*, 268:20277, 1990). According to the Examiner, Kaneda et al. "teach probes comprising a variance of thymidylate synthase gene listed in Table 10 (Figure 2, Genbank Accession No. D00596, page 20277)."

Kaneda et al. does not appear to disclose any of the thymidylate synthase gene variances disclosed in Table 10.

Applicant respectfully requests that the Examiner identify the variance in Table 10 allegedly disclosed by Kaneda et al. and the position of the variance in Figure 2 of Kaneda et al. so that this issue can be resolved.

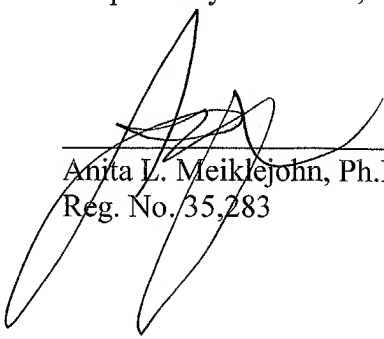
Assuming that Kaneda et al. does not disclose a thymidylate synthase gene variance in Table 10, the cited references, no matter how combined cannot render obvious any of the presently pending claims.

In view of the forgoing, Applicant respectfully requests that the rejections under 35 U.S.C. §103 be withdrawn.

Applicant asks that all claims be allowed. Enclosed is a check in the amount of \$2,609.00 for excess claim fees. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 10 APRIL 2001

  
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